

State of California—Health and Human Services Agency California Department of Public Health



EDMUND G. BROWN JR. Governor

February 21, 2012

TO: ALL INTERESTED PARTIES

SUBJECT: HEPATITIS C COUNSELING AND TESTING, ASSEMBLY BILL 1382

On October 9, 2011, Governor Edmund G. Brown, Jr., signed into law Assembly Bill 1382 (Hernandez, Chapter 643, Statutes of 2011) as part of statewide efforts to increase the number of persons, at risk for hepatitis C virus (HCV) infection, who learn their HCV antibody test results and receive results-specific counseling and referrals. The new law amends California Health and Safety Code Section 120917 to allow trained HIV test counselors who are authorized in California to perform HIV tests waived under the federal Clinical Laboratory Improvement Act (CLIA) to also perform CLIA-waived HCV and combination HIV/HCV tests.¹ HIV test counselors performing CLIA-waived HCV tests will need to meet the same performance and training requirements as they do for CLIA-waived HIV testing. (The enclosed fact sheet has more information for HIV testing sites and HIV test counselors.)

This change in law comes after many years of successful integration of HCV antibody testing into HIV testing sites throughout California. Historically, HCV antibody tests were administered by phlebotomy (blood draw) or through a client self-administered finger-stick test. With these test methods, clients often had to wait two weeks to receive their HCV antibody test results and some people failed to return for their results. Rapid HCV testing will allow clients to receive their test results, as well as results-specific counseling and service referrals, in the same day. Many sites are already performing rapid HIV testing, and should be able to integrate rapid HCV testing into their services.

Similar to HIV, HCV is transmissible through the sharing of contaminated injection equipment, and the majority of injection drug users (IDUs) infected with HIV are dually infected with HCV. Currently in the United States, HCV is ranked the number one

¹ To date, no combination HIV/HCV rapid test has been approved by U.S. Food and Drug Administration (FDA); however, combination HIV/HCV rapid tests are currently in development. State law allows for use of these tests in the event they are approved by FDA and CLIA-waived for use by non-medical personnel.

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cause of death among persons with HIV and is the leading cause of liver transplants nationwide. Yet, an estimated 75 percent of people with HCV are unaware of their infection.

Because of the high prevalence and significant consequences of HIV/HCV co-infection among IDUs and other at-risk groups, the Centers for Disease Control and Prevention recommends testing all individuals living with HIV for HCV and also recommends integrating HCV testing into HIV counseling and testing sites, which target at-risk groups. Early detection of HCV is essential to reducing the likelihood of HCV-related liver disease and other complications, and to preventing further disease transmission.

This law is timely given the FDA approval of the first-ever rapid HCV antibody finger-stick test in February 2011 and the CLIA waiver of that test in November 2011. The California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS (OA) and CDPH's Sexually Transmitted Disease (STD) Control Branch, Office of Adult Viral Hepatitis Prevention are working with community partners to develop training materials on HCV counseling and testing for HIV testing sites. Background information on HIV testing is available at the following link: www.cdph.ca.gov/programs/AIDS/Pages/tOAPrevention.aspx. Additional materials will be accessible at the same location when they are developed.

For more information on HCV, contact Rachel McLean, Adult Viral Hepatitis Prevention Coordinator, STD Control Branch, by phone at (510) 620-3403 or e-mail at: <u>rachel.mclean@cdph.ca.gov</u>. HIV testing sites interested in offering the HCV rapid test and community-based programs interested in becoming an HIV testing site should contact Amy Kile-Puente, HIV Testing and Training Program Consultant, OA, at (916) 449-5805 or <u>Amy.Kile-Puente@cdph.ca.gov</u>.

Sincerely,

Karen Mark, M.D., M.P.H. Interim Chief Office of AIDS

Enclosure

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James Watt, M.D., M.P.H., Chief Division of Communicable Disease Control

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